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February 28, 2005

CERTIFICATE OF MAILING 37 C.F.R 1.8

I certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MS AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:

February 28, 2005

Date

Gina N. Shishima

MS AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

RE:

U.S. Patent Application No. 10/751,606 entitled "OPTIMIZATION OF CANCER

TREATMENT WITH IRINOTECAN" - Mark J. Ratain et al.

Our reference: ARCD:389US Client reference: UCHI 1014

Sir:

Enclosed for filing in the above-referenced patent application is a Supplemental Information Disclosure Statement, Form PTO-1449, and references B6-B16 and C218-C221.

No fees are believed to be due in connection with the filing of this Supplemental Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/ARCD:389US.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

Gina N. Shishima

Reg. No. 45,104

GNS/kvp

Encl.: as noted

164,77770 1





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Mark J. Ratain et al.

Serial No.: 10/751,606

Filed: January 5, 2004

For: OPTIMIZATION OF CANCER TREATMENT WITH IRINOTECAN

Group Art Unit: 1645

Examiner: Unknown

Atty. Dkt. No.: ARCD:389US

CERTIFICATE OF MAILING 37 C.F.R 1.8

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April 30, 2004

Date

Gina N. Shishima

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

MS AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of cited U.S. patents, U. S. patent application publications and co-pending U.S. patent applications have not been enclosed subject to the waiver regarding the requirement under 37 C.F.R. §1.98(a)(2)(i) stated in the Official Gazette Notice dated August 5, 2003 regarding patent applications filed on or after June 30, 2003.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Supplemental Information Disclosure

Statement is not to be construed as a representation that a search has been made, and is not to be

construed to be an admission that the information cited is, or is considered to be, material to

patentability as defined in 37 C.F.R. § 1.56(b).

The present Supplemental Information Disclosure Statement is being filed prior to the

receipt of a first Official Action reflecting an examination on the merits, and hence is believed to

be timely filed in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in

connection with the filing of this Supplemental Information Disclosure Statement, however,

should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to

these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright &

Jaworski Deposit Account No.: 50-1212/ARCD:389US.

Applicants respectfully request that the listed documents be made of record in the present

case.

Respectfully submitted,

Attorney for Applicants

1.

Gina N. Shishima Reg. No. 45,104

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(512) 474-5201

Date:

February 28, 2005

25507376.1

Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No. ARCD:389US

Serial No. 10/751,606

Applicant

Mark Ratain et al.

Filing Date: January 5, 2004 Group: 1645

U.S. Patent Documents

See Page 1

Foreign Patent Documents

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Other Art See Page 2

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A9	2002/0061518	5/28/02	Penny and Galvin	435	6	5/05/99
	A10	2003/0077629	4/24/03	Galvin et al.	435	6	7/24/02
	A11	2003/0099960	5/29/03	Ratain et al.	435	6	1/25/02
	A12	2003/0099977	5/29/03	Guida and Kurth	435	6	7/26/02
	A13	2003/0157517	8/21/03	Penny and Galvin	435	6	9/18/02
	A14	2004/0058363	3/25/04	Hasegawa et al.	435	6	6/12/03
	A15	2004/0076968	4/22/04	Acuna et al.	435	6	7/02/01
	A16	2004/0121327	6/24/04	Manns and Strassburg	435	6	1/03/02
	A17	2004/0203034	10/14/04	Ratain et al.	435	6	1/05/04
	A18	5,972,614	10/1999	Ruano et al.	436	6	
	A19	6,448,003	9/10/2	Guida and Kurth	435	6	6/08/99
	A20	6,586,175	7/01/03	Galvin et al.	435	6	7/20/99

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	В6	JP 2004-073035	3/11/04	Japan			Abstract
	В7	EP 1352970	10/15/03	Europe			English
	В8	WO 01/79230	10/25/01	WIPO			English
	В9	WO 02/053770	7/11/02	WIPO			English
	B10	WO 02/057410	7/25/02	WIPO			English
	B11	WO 02/06523	1/24/02	WIPO			English
	B12	WO 2003/013536	2/20/03	WIPO			English
	B13	WO 2003/013537	2/20/03	WIPO			English

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EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)		Atty. Docket No. ARCD:389US	Serial No. 10/751,606	
List of Patents and Publications for A	pplicant's	Applicant		
		Mark Ratain <i>et al</i> .		
INFORMATION DISCLOSURE STA	TEMENT			
(Use several sheets if necessary))	Filing Date: January 5, 2004	Group: 1645	
U.S. Patent Documents	Foreign P	atent Documents	Other Art	
See Page 1	Se	ee Page 1	See Page 2	

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B14	WO 2004/016814	2/26/04	WIPO			Abstract
	B15	WO 97/32042	9/04/97	WIPO			English
	B16	WO 99/57322	11/11/99	WIPO			English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation				
	C218	Ando et al., "UGTIA1 genotypes and glucuronidation of SN-38, the active metabolite of irinotecan," Annals of Oncology, 9:845-847, 1998.				
	C219	Beutler et al., "Racial variability in the UDP-glucuronosyltransferase 1(UGTlA1) promoter: a balanced polymorphism for regulation of bilirubin metabolism," <i>Proc. Natl. Acad. Sci., USA</i> , 95:8170-8174, 1998.				
	C220	Clarke et al., "Genetic defects of the UDP-glucuronosyltransferase-1 (UGT1) gene that cause familial non-hemolytic unconjugated hyperbilirubinemias," Clinica Chimica Acta, 266:63-74, 1997.				
	C221	De Morais et al., "Decreased glucuronidation and increased bioactivation of Acetaminophen in Gilbert's syndrome," Gastroenterology, 102:577-586, 1992.				

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